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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,381	11/28/2005	Yusuke Nakamura	082368-002810US	8925
20350 7590 12/12/2007 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER POHNERT, STEVEN C	
			ART UNIT 1634	PAPER NUMBER
			MAIL DATE 12/12/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/529,381	<b>Applicant(s)</b> NAKAMURA ET AL.	
	<b>Examiner</b> Steven C. Pohnert	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1, 6 (in part) 31 (in part) and 32 (in part) are drawn to a polypeptide of amino acid SEQ ID NO 4 or 6. (Subject to further restriction).

Group 2, claim(s) 2, 6 (in part), 31 (in part) and 32 (in part) are drawn to a polypeptide of amino acid sequence 2.

Group 3, claim(s) 3-5, 8-9, 20 (in part), 21 (in part), 33 (in part) are drawn to an isolated polynucleotide of claim 1.

Group 4, claim(s) 7, 22 (in part), and 33 (in part) are drawn to antibody.

Group 5, claim(s) 11 and 12, are drawn to method of diagnosing prostate cancer. (Subject to further restriction).

Group 6, claim(s) 13, 23 (in part), 27 (in part), is drawn to a method of screening compounds by ability to bind a polypeptide. (Subject to further restriction).

Group 7, claim(s) 14-15, 23 (in part), 27 (in part), are drawn to method of screening a compound by assaying biological activity. (Subject to further restriction).

Group 8, claim(s) 16-17, 23 (in part), 27 (in part), are drawn to methods of screening compounds by nucleic acid assay. (Subject to further restriction).

Group 9, claim(s) 18, 23 (in part), 27 (in part), is drawn to methods of screening transcriptional activity. (Subject to further restriction).

Group 10, claim(s) 19, 23 (in part), 27 (in part), drawn to methods of screening test compounds by measurement of actin binding.

Group 11, claim(s) 20 (in part), 21 (in part) is drawn to siRNA directed to SEQ ID NO 2.

Group 12, claim(s) 22 (in part), is drawn to an antibody to SEQ ID NO 2.

Group 13, claim(s) 24 and 25, is drawn to methods of treating prostate cancer by siRNA. (Subject to further restriction).

Group 14, claim(s) 26, is drawn to methods of treating prostate cancer by use of antibodies. (Subject to further restriction).

Group 15, claim(s) 28-30 are drawn to methods of inducing tumor immunity. (Subject to further restriction).

2. The inventions listed as Groups 1-15 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The claims are drawn to MICAL2 and PCOTH, nucleic and nucleic acid sequences and methods based on these sequences. As MICAL2 and PCOTH genes were known at the time of the invention (Terman et al (Cell (2002) vol 109, pages 887-900) and GenBank accession NT\_024524.7 gi:17475964). Thus methods requiring nucleic acids and proteins do not have a special technical feature over the prior art. Moreover, since the polynucleotides, proteins, and antibodies are not homologous to each other, they fail to share a common structure, i.e., a significant structural element. The sugar-phosphate backbone cannot be considered a significant structural element, since all nucleic acid molecules share it. Therefore, the nucleic acids, antibodies and polypeptides do not share any significant structural element and cannot be considered as having the same or corresponding technical feature. Therefore, the proteins do not share any significant structural element and cannot be considered as having the same or corresponding technical feature. The mere fact that polynucleotide and protein fragments are derived from the same source (human genome) is not sufficient to meet the criteria for unity of invention. The polynucleotides, proteins, and antibodies fail to share a common property or activity and fail to share a common structure. Since neither of these two requirements is met, the group of polynucleotide molecules claimed does not meet the requirement of unity of invention. As all method are based on the protein or nucleic acid sequence they lack a special technical feature over the prior art as well.

#### **Further Restriction**

3. Additionally, group 1 and 6 named above is subject to further restriction.

4. Applicant must further select a specific SEQ ID NO from claim 1. The amino acid sequence of each SEQ ID NO do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the description fails to disclose that all of the SEQ ID NO share a common structure or function.

5. Additionally, group 6 named above is subject to further restriction.

6. Applicant must further select a specific SEQ ID NO from claim 11. The nucleotide and amino acid sequence of each SEQ ID NO do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the description fails to disclose that all of the SEQ ID NO share a common structure or function. While each amino acid or nucleic sequence of each SEQ ID NO may serve to isolate its own respective full length DNA, due to the lack of homology between the primer pairs, one primer pair cannot be used to amplify the same region of DNA as another.

7. Additionally, group 7 named above is subject to further restriction.

8. Applicant must further select a specific SEQ ID NO from claim 13. The nucleotide and amino acid sequence of each SEQ ID NO do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the description fails to disclose that all of the SEQ ID NO share a common structure or function, or encode the same protein. While each amino acid or nucleic sequence of

each SEQ ID NO may serve to isolate its own respective full length DNA, due to the lack of homology between the primer pairs, one primer pair cannot be used to amplify the same region of DNA as another.

9. Additionally, group 8 named above is subject to further restriction.

10. Applicant must further select a specific SEQ ID NO from claim 14. The nucleotide and amino acid sequence of each SEQ ID NO do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the description fails to disclose that all of the SEQ ID NO share a common structure or function or encode the same protein. While each amino acid or nucleic sequence of each SEQ ID NO may serve to isolate its own respective full length DNA, due to the lack of homology between the primer pairs, one primer pair cannot be used to amplify the same region of DNA as another.

11. Additionally, group 9 named above is subject to further restriction.

12. Applicant must further select a specific SEQ ID NO from claim 16. The nucleotide sequence of each SEQ ID NO do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the description fails to disclose that all of the SEQ ID NO share a common property, activity, or encode the same protein. While each nucleic sequence of each SEQ ID NO may serve to isolate its own respective full length DNA, due to the lack of homology between the primer pairs, one primer pair cannot be used to amplify the same region of DNA as another.

13. Additionally, group 10 named above is subject to further restriction.
14. Applicant must further select a specific SEQ ID NO from claim 18. The nucleotide sequence of each SEQ ID NO do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the description fails to disclose that all of the SEQ ID NO share a common structure or function or encode the same protein . While each nucleic sequence of each SEQ ID NO may serve to isolate its own respective full length DNA, due to the lack of homology between the primer pairs, one primer pair cannot be used to amplify the same region of DNA as another.
15. Additionally, group 14 named above is subject to further restriction.
16. Applicant must further select a specific SEQ ID NO from claim 24 and the corresponding siRNA sequence from claim 25. The nucleotide sequence of each SEQ ID NO do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the description fails to disclose that all of the SEQ ID NO share a common structure or function. While each amino acid or nucleic sequence of each SEQ ID NO may serve to isolate its own respective full length DNA, due to the lack of homology between the primer pairs, one primer pair cannot be used to amplify the same region of DNA as another.
17. Additionally, group 15 named above is subject to further restriction.

18. Applicant must further select a specific SEQ ID NO from claim 26. The nucleotide and amino acid sequence of each SEQ ID NO do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the description fails to disclose that all of the SEQ ID NO share a common structure, function, or encode the same protein. While each amino acid or nucleic sequence of each SEQ ID NO may serve to isolate its own respective full length DNA, due to the lack of homology between the primer pairs, one primer pair cannot be used to amplify the same region of DNA as another.

19. Additionally, group 16 named above is subject to further restriction.

20. Applicant must further select a specific SEQ ID NO. The nucleotide and amino acid sequence of each SEQ ID NO do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the description fails to disclose that all of the SEQ ID NO share a common structure, function, or encode the same protein. While each amino acid or nucleic sequence of each SEQ ID NO may serve to isolate its own respective full length DNA, due to the lack of homology between the primer pairs, one primer pair cannot be used to amplify the same region of DNA as another.

21. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are

subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

22. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

23. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven C. Pohnert whose telephone number is 571-272-3803. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'S. Pohnert', with a stylized flourish at the end.

Steven Pohnert

/Carla Myers/  
Primary Examiner, AU 1634